REMARKS

Claims 5, 6, 9, 12-14, 39 and 42 are pending upon entry of the above amendments. Claim 9 is amended herein to correct a typographical error. No new matter is introduced.

Objections

The specification is objected to because the Examiner contends that it contains an embedded hyperlink at page 170. The text the Examiner objects to is as follows:

> "The SAGE expression profiles reported in this invention are generated by first identifying the Unigene accession ID associated with the given MTC gene by querying the Unigene database at http://www.ncbi.nlm.nih.gov/UniGene/. This page has then a link to the SAGE : Gene to Tag mapping (http://www.ncbi.nlm.nih.gov/SAGE/SAGEcid.cgi?cid="unigeneID")."

However, the MPEP §608.01 states:

> "Where the hyperlinks and/or other forms of browser-executable codes themselves rather than the contents of the site to which the hyperlinks are directed are part of applicant's invention and it is necessary to have them included in the patent application in order to comply with the requirements of 35 U.S.C. 112, first paragraph, and applicant does not intend to have these hyperlinks be active links, examiners should not object to these hyperlinks."

As this is the situation in the present case, Applicants believe that correction should not be required.

Rejections under 35 U.S.C. § 112, first paragraph

Claim 6 is rejected under 35 U.S.C. § 112, first paragraph, as failing to comply with the written description requirement as containing subject matter which was not described in the specification in such a way as to reasonably convey to one of skill in the art, that the inventors, at the time the application was filed, had possession of the claimed invention.

Claim 6 has been rejected as the Examiner alleges that the written description is not commensurate in scope to the claim that reads on any sequence that is complementary to that of SEQ ID NO:1. Applicant respectfully disagrees. It is well known in the art that the complement of a first nucleic acid sequence is a matching nucleic acid sequence, in which each base is the matched pair of the base in the corresponding position of the first nucleic acid sequence, the

matched pairs being adenine:thymine and guanine:cytosine. In the specification, at page 63, lines 23-27, it says:

> "In another embodiment, an isolated nucleic acid molecule of the invention comprises a nucleic acid molecule that is a complement of the nucleotide sequence shown in SEQ ID NOS:1, 3, 5, 7, 9, and 11, or a portion of this nucleotide sequence (*e.g.*, a fragment that can be used as a probe or primer or a fragment encoding a biologically-active portion of an NOVX polypeptide)." Emphysis added.

It is clear that the *complement* of a nucleotide sequence of a specific SEQ ID NO is intended to mean a full length nucleotide sequence comprising the matched base pair at each position of the full length sequence defined by the SEQ ID NO. If anything less than the full length is intended, the specification specifies a complement of a portion of the nucleotide sequence defined by the SEQ ID NO (or fragment or other appropriate term).

Applicant respectfully submits that "a complement" should not be confused with "a complementary" nucleic acid. A *complementary* nucleic acid molecule is referred to as:

> "A nucleic acid molecule that is complementary to the nucleotide sequence shown SEQ ID NOS:1, 3, 5, 7, 9, or 11 is one that is sufficiently complementary to the nucleotide sequence shown SEQ ID NOS:1, 3, 5, 7, 9, or 11 that it can hydrogen bond with little or no mismatches to the nucleotide sequence shown SEQ ID NOS:1, 3, 5, 7, 9, and 11, thereby forming a stable duplex." See instant specification, page 63, lines 27-31.

Thus, a *complementary* nucleic acid sequence may be a full-length complement, or a portion thereof. As such, the use of complement is clear and is intended to mean, the full complement of SEQ ID NO:1 in currently pending claim 6. Applicants respectfully request that the rejection be withdrawn.

Rejection under 35 U.S.C. §101

Claims 5, 6, 9, 12-14, 39 and 42 are rejected under 35 U.S.C.§101. The Examiner alleges that the claimed invention is not supported by either a specific asserted utility or a well established utility.

Applicant respectfully traverses this rejection. Under 35 U.S.C. §101, what is required is the assertion of a utility that is specific, substantial and credible. Applicant has asserted such a utility for the claimed invention in the specification. For example, at page 9 and Table 9 at page 140, the specification teaches that NOV1 is found overexpressed in kidney tumors. Utilizing the methods taught in the present specification beginning at page 130, expression levels of NOV1 may be detected in normal and malignant kidney cells and/or tissues and can be used as a marker of disease. One of skill in the art, having read the specification, would therefore know to detect and compare the amount of expression of NOV1 in samples of pathological and normal tissues, by using, e.g. RTQ-PCR methods as described in the specification to differentiate malignant kidney tissue from normal tissues.

The utility described above is specific and substantial. Applicants have not suggested that NOV1 be used in a general undefined way or for diagnosing an unspecified disease. Since Applicants have made an assertion that the claimed invention is useful for a particular purpose, and such assertion would be considered credible by a person of ordinary skill in the art, a rejection based on lack of utility is not proper.

The Examiner relies upon Bowie et al. (Science 1990, 257:1306-1310); Burgess et al (J Cell Bio. 111:2129-2138, 1990); Scott et al (Nature Genetics, 1999, 21:440-443); and Bork (Genome Research, 2000, 10:398-400) to support the rejection of claims 5, 6, 9, 12-14, 39 and 42 under 35 U.S.C.§101. According to the Examiner, Bowie supports that evidence based on protein sequence homology does not alone permit extrapolation to an isolated *amino acid's* biological function or use thereof. Burgess exemplifies the sensitivity of *proteins* to alterations of even a single *amino acid.* Scott suggests the importance of confirming the function of newly identified *gene products* even when the database searches reveal significant homology to *proteins* of known function. Bork teaches the pitfalls associated with comparative sequence analysis for predicting *protein* function because of the known error margins for high-throughput computational methods. Applicants respectfully point out that each reference, Bowie, Burgess, Scott and Bork are relied upon in terms of not being able to predict the biological function of a ***protein*** based upon homology to a known protein; ***however*** the pending claims pertain to an isolated ***nucleic acid.*** Therefore these references are not relevant and do not support the rejection of claims 5, 6, 9, 12-14, 39 and 42 under 35 U.S.C.§101.

The Examiner himself has pointed out that:

> "According to the Federal Guidelines (Fed. Reg. Vol.66, No. 4, January 5, 2001), an isolated and purified nucleic acid molecule may meet the statutory utility requirement if, e.g. it can be used to produce a useful protein or it hybridizes near and serves as a marker for a disease gene."

The Examiner contends that the specification does not teach a relationship to any specific disease. Applicant respectfully submits that the specification clearly shows a relationship between NOV1 gene overexpression and kidney cancer.

The Examiner further relies upon Jansen, Alberts, Shantz, McClean, Fu, Yokota to support the contention that protein translation is a highly regulated event and that expression of mRNA specific for a tissue type does not dictate nor predict the translation of such mRNA into a polypeptide. While the Examiner has not provided these references for Applicant's review, Applicant respectfully submits that regulation of protein expression is not relevant to Applicant's pending claims pertaining to nucleic acid molecules and such references would not support the rejection of claims 5, 6, 9, 12-14, 39 and 42 under 35 U.S.C.§101.

Applicants respectfully request the rejection be withdrawn.

Rejections under 35 U.S.C. § 112, first paragraph

Claims 5, 6, 9, 12-14, 39 and 42 are rejected under 35 U.S.C. §112 first paragraph as allegedly not supported by either a substantial asserted utility or a well established utility so that one of skill in the art would not know how to use the claimed invention.

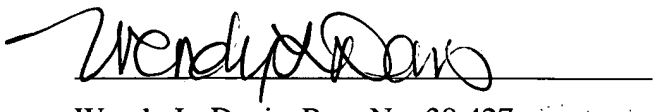
Applicants respectfully disagree. As discussed above, a specific and substantial utility for the claimed invention is taught in the specification. Applicants respectfully request that the rejection be withdrawn.

CONCLUSION

Applicant respectfully requests that the amendments and remarks made herein be entered and made of record in the file history of the present application. Applicant respectfully submits that this paper is fully responsive and that the pending claims are in condition for allowance. Such action is respectfully requested. If there are any questions regarding these amendments and

remarks, the Examiner is encouraged to contact the undersigned at the telephone number provided below.

Respectfully submitted,



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